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Attorneys for Plaintiffs
SENJU PHARMACEUTICAL CO., LTD.
BAUSCH & LOMB INCORPORATED, and
BAUSCH & LOMB PHARMA HOLDINGS CORP.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SENJU PHARMACEUTICAL CO., LTD.,)	
BAUSCH & LOMB INCORPORATED and)	
BAUSCH & LOMB PHARMA HOLDINGS)	
CORP.)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No.:
)	
HI-TECH PHARMACAL CO. INC., AKORN,)	
INC. and AKORN OPHTHALMICS, INC.)	
)	
)	
Defendants.)	
)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Senju Pharmaceutical Co., Ltd., Bausch & Lomb Incorporated and Bausch & Lomb Pharma Holdings Corp. (collectively, “Plaintiffs”) by way of Complaint against Defendants Hi-Tech Pharmacal Co. Inc. (“Hi-Tech”), Akorn, Inc. and Akorn Ophthalmics, Inc. (collectively, “Defendants”) allege as follows:

THE PARTIES

1. Plaintiff Senju Pharmaceutical Co., Ltd. (“Senju”) is a corporation organized and existing under the laws of Japan, with a principal place of business at 2-5-8, Hirano-machi, Chuo-ku, Osaka 541-0046, Japan.

2. Plaintiff Bausch & Lomb Incorporated (“B+L”) is a corporation organized and existing under the laws of New York, with a place of business at 1400 North Goodman St., Rochester, New York 14609. B+L is the registered holder of approved New Drug Application No. 203168, which covers Prolensa[®].

3. Plaintiff Bausch & Lomb Pharma Holdings Corp. (“B+L Pharma Holdings”) is a corporation organized and existing under the laws of Delaware, with a place of business at 700 Route 202/206, Bridgewater, New Jersey 08807. B+L Pharma Holdings is a wholly-owned subsidiary of B+L.

4. Upon information and belief, defendant Hi-Tech is a corporation organized and existing under the laws of Delaware, having a principal place of business at 369 Bayview Avenue, Amityville, NY 11701. Upon information and belief, Hi-Tech is a wholly-owned subsidiary of Akorn, Inc.

5. Upon information and belief, defendant Akorn, Inc. is a corporation organized and existing under the laws of Louisiana, having a principal place of business at 1925 West Field Court, Suite 300, Lake Forest, Illinois 60045. Akorn, Inc.’s registered agent for service of process in New Jersey is Corporation Service Company, 830 Bear Tavern Road, West Trenton, NJ 08628.

6. Upon information and belief, defendant Akorn Ophthalmics, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1925

West Field Court, Suite 300, Lake Forest Illinois 60045. Upon information and belief, Akorn Ophthalmics, Inc. is a wholly-owned subsidiary of Akorn, Inc.

NATURE OF THE ACTION

7. This is an action for infringement of United States Patent Nos. 8,129,431 (“the ’431 patent”), 8,669,290 (“the ’290 patent”), 8,754,131 (“the ’131 patent”), 8,871,813 (“the ’813 patent”), 8,927,606 (“the ’606 patent”) and 9,144,609 (“the ’609 patent”), arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Hi-Tech’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market generic Bromfenac Ophthalmic Solution 0.07% (“Hi-Tech’s generic bromfenac ophthalmic solution”).

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

9. Upon information and belief, this Court has jurisdiction over Hi-Tech. Upon information and belief, Hi-Tech is in the business of licensing, manufacturing, distributing and selling pharmaceutical products, including generic drug products. Upon information and belief, Hi-Tech directly licenses, manufactures, markets and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for the Hi-Tech’s generic bromfenac ophthalmic solution. Upon information and belief, Hi-Tech purposefully has conducted and continues to conduct business in this judicial district.

10. Upon information and belief, this Court has jurisdiction over Akorn, Inc. Upon information and belief, Akorn, Inc. is in the business of licensing, manufacturing, distributing and selling pharmaceutical products, including generic drug products. Upon information and

belief, Akorn, Inc. directly licenses, manufactures, markets and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Hi-Tech's generic bromfenac ophthalmic solution. Upon information and belief, Akorn, Inc. purposefully has conducted and continues to conduct business in this judicial district.

11. Upon information and belief, this court has jurisdiction over Akorn Ophthalmics, Inc. Upon information and belief, Akorn Ophthalmics, Inc. directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Hi-Tech and/or Akorn, Inc., throughout the United States and in this judicial district. Upon information and belief, Akorn Ophthalmics, Inc. purposefully has conducted and continues to conduct business in this judicial district.

12. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

THE PATENTS IN SUIT

13. The U.S. Patent and Trademark Office ("PTO") issued the '431 patent on March 6, 2012. The '431 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '431 patent and have the right to sue for infringement thereof. Senju is the assignee of the '431 patent. A copy of the '431 patent is attached hereto as Exhibit A.

14. The PTO issued the '290 patent on March 11, 2014. The '290 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '290 patent and have the right to sue for infringement thereof. Senju is the assignee of the '290 patent. A copy of the '290 patent is attached hereto as Exhibit B.

15. The PTO issued the '131 patent on June 17, 2014. The '131 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial

rights in the '131 patent and have the right to sue for infringement thereof. Senju is the assignee of the '131 patent. A copy of the '131 patent is attached hereto as Exhibit C.

16. The PTO issued the '813 patent on October 28, 2014. The '813 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '813 patent and have the right to sue for infringement thereof. Senju is the assignee of the '813 patent. A copy of the '813 patent is attached hereto as Exhibit D.

17. The PTO issued the '606 patent on January 6, 2015. The '606 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '606 patent and have the right to sue for infringement thereof. Senju is the assignee of the '606 patent. A copy of the '606 patent is attached hereto as Exhibit E.

18. The PTO issued the '609 patent on September 29, 2015. The '609 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '609 patent and have the right to sue for infringement thereof. Senju is the assignee of the '609 patent. A copy of the '609 patent is attached hereto as Exhibit F.

19. B+L is the holder of New Drug Application ("NDA") No. 203168 for Prolensa[®], which the FDA approved on April 5, 2013. In conjunction with NDA No. 203168, the '431 patent, the '290 patent, the '131 patent, the '813 patent, the '606 patent and the '609 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

20. Bromfenac Ophthalmic Solution 0.07% is sold in the United States under the trademark Prolensa[®].

DEFENDANTS' INFRINGING ANDA SUBMISSION

21. Upon information and belief, Hi-Tech filed with the FDA ANDA No. 208985, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

22. Upon information and belief, Hi-Tech's ANDA No. 208985 seeks FDA approval to sell in the United States Hi-Tech's generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa[®].

23. Plaintiffs received a letter from Hi-Tech dated March 10, 2016, purporting to be a Notice of Certification for ANDA No. 208985 ("Hi-Tech's notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c).

24. Hi-Tech's notice letter alleges that Hi-Tech has submitted to the FDA ANDA No. 208985 seeking FDA approval to sell generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa[®].

25. Upon information and belief, ANDA No. 208985 seeks approval of Hi-Tech's generic bromfenac ophthalmic solution that is the same, or substantially the same, as Prolensa[®].

26. Upon information and belief, Hi-Tech's actions relating to ANDA No. 208985 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Akorn, Inc. and Akorn Ophthalmics, Inc.

COUNT I

Infringement of the '431 Patent under § 271(e)(2)

27. Paragraphs 1-26 are incorporated herein as set forth above.

28. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '431 patent by Hi-Tech's submitting, or causing to be submitted to the FDA, ANDA No. 208985 seeking approval for the commercial marketing of Hi-Tech's generic bromfenac ophthalmic solution before the expiration date of the '431 patent.

29. Upon information and belief, Hi-Tech's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '431 patent.

30. Upon information and belief, Defendants will, through the manufacture, use import, offer for sale and/or sale of Hi-Tech's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '431 patent.

COUNT II

Declaratory Judgment of Infringement of the '431 Patent

31. Paragraphs 1-30 are incorporated herein as set forth above. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

32. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

33. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Hi-Tech's generic bromfenac ophthalmic solution before the expiration date of the '431 patent, including Hi-Tech's filing of ANDA No. 208985.

34. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '431 patent.

35. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '431 patent.

COUNT III

Infringement of the '290 patent under § 271(e)(2)

36. Paragraphs 1-35 are incorporated herein as set forth above.

37. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '290 patent by Hi-Tech's submitting, or causing to be submitted to the FDA, ANDA No. 208985 seeking approval for the commercial marketing of Hi-Tech's generic bromfenac ophthalmic solution before the expiration date of the '290 patent.

38. Upon information and belief, Hi-Tech's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '290 patent.

39. Upon information and belief, Defendants will, through the manufacture, use import, offer for sale and/or sale of Hi-Tech's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '290 patent.

COUNT IV

Declaratory Judgment of Infringement of the '290 Patent

40. Paragraphs 1-39 are incorporated herein as set forth above.

41. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

42. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

43. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Hi-Tech's generic bromfenac

ophthalmic solution before the expiration date of the '290 patent, including Hi-Tech's filing of ANDA No. 208985.

44. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '290 patent.

45. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '290 patent.

COUNT V

Infringement of the '131 patent under § 271(e)(2)

46. Paragraphs 1-45 are incorporated herein as set forth above.

47. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '131 patent by Hi-Tech's submitting, or causing to be submitted to the FDA, ANDA No. 208985 seeking approval for the commercial marketing of Hi-Tech's generic bromfenac ophthalmic solution before the expiration date of the '131 patent.

48. Upon information and belief, Hi-Tech's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '131 patent.

49. Upon information and belief, Defendants will, through the manufacture, use import, offer for sale and/or sale of Hi-Tech's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '131 patent.

COUNT VI

Declaratory Judgment of Infringement of the '131 Patent

50. Paragraphs 1-49 are incorporated herein as set forth above.

51. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

52. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

53. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Hi-Tech's generic bromfenac ophthalmic solution before the expiration date of the '131 patent, including Hi-Tech's filing of ANDA No. 208985.

54. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '131 patent.

55. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '131 patent.

COUNT VII

Infringement of the '813 patent under § 271(e)(2)

56. Paragraphs 1-55 are incorporated herein as set forth above.

57. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '813 patent by Hi-Tech's submitting, or causing to be submitted to the FDA, ANDA No. 208985

seeking approval for the commercial marketing of Hi-Tech's generic bromfenac ophthalmic solution before the expiration date of the '813 patent.

58. Upon information and belief, Hi-Tech's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '813 patent.

59. Upon information and belief, Defendants will, through the manufacture, use import, offer for sale and/or sale of Hi-Tech's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '813 patent.

COUNT VIII

Declaratory Judgment of Infringement of the '813 Patent

60. Paragraphs 1-59 are incorporated herein as set forth above.

61. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

62. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

63. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Hi-Tech's generic bromfenac ophthalmic solution before the expiration date of the '813 patent, including Hi-Tech's filing of ANDA No. 208985.

64. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's generic bromfenac ophthalmic solution will directly

infringe, contributorily infringe and/or induce infringement of at least one claim of the '813 patent.

65. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '813 patent.

COUNT IX

Infringement of the '606 Patent under § 271(e)(2)

66. Paragraphs 1-65 are incorporated herein as set forth above.

67. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '606 patent by Hi-Tech's submitting, or causing to be submitted to the FDA, ANDA No. 208985 seeking approval for the commercial marketing of Hi-Tech's generic bromfenac ophthalmic solution before the expiration date of the '606 patent.

68. Upon information and belief, Hi-Tech's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '606 patent.

69. Upon information and belief, Defendants will, through the manufacture, use import, offer for sale and/or sale of Hi-Tech's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '606 patent.

COUNT X

Declaratory Judgment of Infringement of the '606 Patent

70. Paragraphs 1-69 are incorporated herein as set forth above.

71. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

72. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

73. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Hi-Tech's generic bromfenac ophthalmic solution before the expiration date of the '606 patent, including Hi-Tech's filing of ANDA No. 208985.

74. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '606 patent.

75. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '606 patent.

COUNT XI

Infringement of the '609 patent under § 271(e)(2)

76. Paragraphs 1-75 are incorporated herein as set forth above.

77. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '609 patent by Hi-Tech's submitting, or causing to be submitted to the FDA, ANDA No. 208985 seeking approval for the commercial marketing of Hi-Tech's generic bromfenac ophthalmic solution before the expiration date of the '609 patent.

78. Upon information and belief, Hi-Tech's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '609 patent.

79. Upon information and belief, Defendants will, through the manufacture, use import, offer for sale and/or sale of Hi-Tech's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '609 patent.

COUNT XII

Declaratory Judgment of Infringement of the '609 Patent

80. Paragraphs 1-79 are incorporated herein as set forth above.

81. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

82. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

83. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Hi-Tech's generic bromfenac ophthalmic solution before the expiration date of the '609 patent, including Hi-Tech's filing of ANDA No. 208985.

84. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '609 patent.

85. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '609 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Defendants on the patent infringement claim set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '431 patent through Hi-Tech's submission of ANDA No. 208985 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Hi-Tech's generic bromfenac ophthalmic solution before the expiration of the '431 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '290 patent through Hi-Tech's submission of ANDA No. 208985 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Hi-Tech's generic bromfenac ophthalmic solution before the expiration of the '290 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '131 patent through Hi-Tech's submission of ANDA No. 208985 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Hi-Tech's generic bromfenac ophthalmic solution before the expiration of the '131 patent;

4. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '813 patent through Hi-Tech's submission of ANDA No. 208985 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in

the United States of Hi-Tech's generic bromfenac ophthalmic solution before the expiration of the '813 patent;

5. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '606 patent through Hi-Tech's submission of ANDA No. 208985 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Hi-Tech's generic bromfenac ophthalmic solution before the expiration of the '606 patent;

6. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '609 patent through Hi-Tech's submission of ANDA No. 208985 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Hi-Tech's generic bromfenac ophthalmic solution before the expiration of the '609 patent;

7. order that the effective date of any approval by the FDA of Hi-Tech's generic bromfenac ophthalmic solution be a date that is not earlier than the expiration of the '431 patent, the '290 patent, the '131 patent, the '813 patent, the '606 patent and the '609 patent, or such later date as the Court may determine;

8. enjoin Defendants from the commercial manufacture, use, import, offer for sale and/or sale of Hi-Tech's generic bromfenac ophthalmic solution until expiration the '431 patent, the '290 patent, the '131 patent, the '813 patent, the '606 patent and the '609 patent, or such later date as the Court may determine;

9. enjoin Defendants and all persons acting in concert with Defendants from seeking, obtaining or maintaining approval of Hi-Tech's ANDA No. 208985 until expiration of the '609 patent;

10. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses and disbursements in this action, including reasonable attorneys' fees;

11. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: April 22, 2016

Respectfully submitted,

s/ Melissa A. Chuderewicz

Melissa A. Chuderewicz

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